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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,108	07/21/2000	SUSAN ANN CHARMAN	13627	9165

7590

04/09/2002

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GARDEN CITY, NY 11530

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/555,108

Applicant(s)  
Charman et al

Examiner  
Karen Canella

Art Unit  
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-18, 20-26, 28-30, 32, and 34-55 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-18, 20-26, 28-30, 32, and 34-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

***Response to Amendment***

1. Please note that the examiner assigned to this application has changed.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. Claims 4, 5, 19, 27, 31 and 33 have been canceled. Claims 44-55 have been added. Claims 1-3, 6-18, 20-26, 28-30, 32, 34-55 are under consideration.
4. The amendment filed January 11, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:
  - the addition of additives for maintaining pH and isotonicity to page 2,
  - the addition of the text on page 5
  - the addition of and/or additives on page 10
  - the addition of other ingredients of the composition on page 11
  - the addition of preservatives on page 12
  - the addition of additives on page 14
  - the addition of pH 5.0 on page 24
  - the deletion of "0.05 or" from page 49 which alters the teaching of the original filing
  - the deletion of text under the heading of Ion Exchange which deletes the teachings regarding the optimal and least optimal embodiments..Applicant is required to cancel the new matter in the reply to this Office action.
5. The specification is objected to as it lacks page 4.

***Claim Rejections Maintained***

6. The rejection of claim 6 under 112, second paragraph, as it is not clear what chemical structures are encompassed by derivatives or homologs of LIF is maintained for reasons of record. Applicant argues that derivatives and homologs of LIF are taught on page 4 of the specification. The specification is missing page 4.

7. The rejection of claims 1-3, 6-13, 15, 16, 20-26, 28, 29, 32 and 34-40, as being anticipated by Patterson et al (US 6,156,729) is maintained for reasons of record. The rejection of newly added claims 47, 50, 51, drawn to polysorbates, are made for the same reasons of record. Patterson teaches stabilized LIF formulations comprising polyethylene glycol. Polysorbate is a polyethylene glycol.

Applicant has provided a Declaration pursuant to 37 CFR 1.131 of Susan Charman in order to establish that the instant invention was conceived before the effective date of the Patterson reference. However, this is an inappropriate Declaration, as the MPEP(715) teaches that a prior invention may not be established under 1.131 if the rejection is based upon a US patent to another which claims the same patentable invention as the instant claims.

8. The rejection of claims 1-3, 6-18, 20-26, 28-30, 32, 34-55 as being unpatentable over Patterson (US 6,156,729) <sup>priority to 10/15147</sup> in view of Cleland (Crit Rev Therapeutic Drug Carrier Systems, 1993, Vol. 10, pp. 307-377), is maintained for reasons of record. The rejection of newly added claims 44-55 are made for the same reasons of record.


Applicant argues that the combination of Patterson and Cleland does not render obvious the instant claims as Cleland does not teach the stabilization of LIF. This has been considered but not found persuasive. Cleland teaches the stabilization of therapeutic protein formulations. Patterson et al teaches LIF in a therapeutic protein formulation comprising physiologically acceptable stabilizers. Therefore, one of skill in the art would be motivated to apply the teachings of Cleland to the LIF formulation of Patterson.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
ANTHONY C. CAPUTA  
SUPERVISOR, PATENT EXAMINER  
TECHNOLOGY CENTER 1642

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
April 8, 2002